

Radiologic Procedure	Rating	Comments	RRL*
MRA abdomen without and with contrast	8	Requires intravenous gadolinium contrast agents and is accurate in diagnosing renal artery stenosis. MRA and CTA are alternative examinations. See statement regarding contrast in text under "Anticipated Exceptions."	O
CTA abdomen with contrast	8	Similar to MRA in accuracy; requires intravenous iodinated contrast media. MRA and CTA are alternative examinations.	☢☢☢
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		Relative to MRA with contrast; considered appropriate for use in patients	*Relative Radiation Level

Radiologic Procedure	Rating	Comments	RRL*
US kidney retroperitoneal with Doppler	6	with impaired renal function. Useful if there is a dedicated team of physicians and technologists who are skilled in the examination.	O
ACE-inhibitor renography	6	Although the technique has not been standardized, it appears to have a relatively high sensitivity and specificity in patients with normal renal function.	☢☢☢
Intraarterial angiography kidney (IADSA)	4	Considered the gold standard for diagnosing renal artery stenosis, but it is invasive. Probably not indicated as primary diagnostic method but must be performed prior to transluminal angioplasty. Reserved for confirmation and for angioplasty or stent placement.	☢☢☢
Renal vein renin assays	3	Should not be used as a screening test but rather to confirm the clinical significance of a renal artery stenosis.	Varies
X-ray intravenous urography	1	Significantly less sensitive than other examinations.	☢☢☢
Intravenous angiography kidney (IVDSA)	1	Difficult to perform on a reliable basis due to high number of inadequate studies.	Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: High index of suspicion of renovascular hypertension and diminished renal function.

Radiologic Procedure	Rating	Comments	RRL*
MRA abdomen without and with contrast	8	Useful in older patients with arteriosclerotic vascular disease (ASVD) with diminished renal function who most likely have proximal renal artery stenosis. MRA and US are complementary examinations. See statement regarding contrast in text under "Anticipated Exceptions."	O
MRA abdomen without contrast	8	Accuracy approaches that of contrast-enhanced MRA, but avoids risk of nephrogenic system fibrosis in those with severe renal impairment. MRA and US are complementary examinations.	O
US kidney retroperitoneal with Doppler	8	Reliable if there is a dedicated team of physicians and technologists who are skilled in the examination. MRA and US are complementary examinations.	O
ACE-inhibitor renography	4	Although diminished renal function can affect the sensitivity and specificity of the examination, it is still reliable as a screening tool.	☢☢☢
Intraarterial angiography kidney (IADSA)	4	Better than conventional angiography because it requires less contrast media. It is often used to guide angioplasty or stent placement.	☢☢☢
Renal vein renin assays	3	Should not be used as a screening examination.	Varies
X-ray intravenous urography	1	Significantly less sensitive than other examinations and uses contrast media.	☢☢☢
Intravenous angiography kidney (IVDSA)	1	Not indicated because of large contrast load to the kidneys.	Varies
CTA abdomen with contrast	1	Not indicated because of large contrast load to kidneys.	☢☢☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative

Radiologic Procedure	Rating	Comments	Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Low index of suspicion of renovascular hypertension ("essential" hypertension).

Radiologic Procedure	Rating	Comments	RRL*
X-ray intravenous urography	1		☢ ☢ ☢
Intraarterial angiography kidney (IADSA)	1		☢ ☢ ☢
US kidney retroperitoneal with Doppler	1		O
Intravenous angiography kidney (IVDSA)	1		Varies
Renal vein renin assays	1		Varies
ACE-inhibitor renography	1		☢ ☢ ☢
CTA abdomen with contrast	1		☢ ☢ ☢
MRA abdomen without and with contrast	1		O
MRA abdomen without contrast	1		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

Hypertension is a common condition affecting approximately 20% of adults. Secondary hypertension (i.e., hypertension with a demonstrable cause) accounts for only 5% to 10% of all cases of hypertension, with the remaining cases considered essential hypertension. Renovascular hypertension is the most common type of secondary hypertension and is estimated to have a prevalence between 0.5% and 5% of the general hypertensive population, and it has an even higher prevalence among patients with severe hypertension and end-stage renal disease, approaching 25% in elderly dialysis patients. There are varied causes of reduced renal perfusion with resultant renovascular hypertension, the most common being renal artery stenosis secondary to either atherosclerotic disease (90%) or fibromuscular dysplasia (10%). Other less common etiologies include vasculitis, embolic disease, dissection, posttraumatic occlusion, and extrinsic compression of a renal artery or of a kidney.

A critical problem in diagnosing renovascular hypertension is the selection of an appropriate end point against which to judge the accuracy of new tests. Calculations of the sensitivity, specificity, and accuracy of these examinations are normally based on a comparison with a standard such as conventional angiography. However, the definition of a significant renal artery stenosis has varied. Most investigators consider a 50%-60% stenosis to be significant, yet perfusion pressure in a large artery is generally not reduced until stenosis exceeds 70%-75%. Ultimately, the defining criterion for renovascular hypertension is a fall in blood pressure after intervention (angioplasty, intravascular stent placement, or surgery). Bilateral renal artery disease remains a problem in that it is difficult in such cases to quantify the effect on blood pressure of one side versus the other.

Because of the low prevalence of renovascular hypertension among hypertensive patients in general, screening examinations on an unselected population without clinical features suggestive of renovascular hypertension are prone to false-positive results. To improve the predictive value of diagnostic imaging examinations, imaging ideally is performed for those persons having clinical features associated with an increased likelihood of renovascular hypertension, such as an abdominal bruit, malignant or accelerated hypertension, significant (diastolic pressure >110 mm Hg) hypertension in a young adult (<35 years of age), new onset after age 50, sudden development or worsening of hypertension, refractory hypertension, deterioration of renal function in response to angiotensin converting enzyme (ACE) inhibitors, and generalized arteriosclerotic occlusive disease with hypertension.

The following is a discussion of the diagnostic imaging examinations for renovascular hypertension due to renal artery stenosis.

Intravenous Urography

Rapid-sequence intravenous urography (IVU) was first used in the late 1950s and 1960s as a screening test for renal artery stenosis, with disparity in renal length, delayed opacification of renal calyces, and hyperconcentration of urine on delayed images taken as potential indicators of reduced renal arterial blood flow. In 1972 one group of investigators reviewed data from the 15-institution Cooperative Study of Renovascular Hypertension and reported 84% sensitivity and 88.6% specificity for detection of renal artery stenosis, though the study did not find that urography was able to predict a positive response to surgery. A later reevaluation of the Cooperative Study data by another group of researchers in 1982 showed a recalculated sensitivity of 78% and specificity of 77.8%, and the authors concluded that urography is not an effective screening tool. A meta-analysis conducted in 1985 calculated a sensitivity of 74.5% and specificity of 86.2% based on pooled data from 12 studies. A 1992 retrospective review of rapid-sequence IVU for 241 patients demonstrated that in a subset of patients with clinical features suggesting renovascular hypertension (i.e., patients with a higher prevalence of renovascular hypertension), rapid-sequence IVU has a negative predictive value of 93% but a positive predictive value of only 57%. IVU currently does not have a role in the evaluation of suspected renovascular hypertension and is not used as a screening test.

Intra-arterial Digital Subtraction Angiography

Intra-arterial digital subtraction angiography (IADSA) is considered the gold standard for demonstrating renal artery stenosis and is an integral part of angioplasty and stenting procedures. Arterial angiography has high spatial resolution for evaluating the main renal arteries as well as the branch renal arteries. There is high interobserver agreement for identification of severe stenoses by angiography, but there is reported substantial interobserver variability in visual estimation of moderate renal artery stenoses. Measurement of pressure gradients across a stenosis allows for functional evaluation of the hemodynamic significance of a renal artery stenosis prior to intervention. A pressure gradient greater than 20 mm Hg or greater than 10% of mean arterial pressure is considered to be an indicator of hemodynamic significance. Carbon dioxide and gadolinium-based agents have both been used as alternatives to iodinated contrast in patients for whom iodinated contrast is contraindicated, but in general, images obtained with these alternative contrast agents are inferior compared to those obtained with iodinated contrast material. As IADSA is an invasive procedure with associated risks of vascular injury and bleeding, entails the use of iodinated contrast and ionizing radiation, and is expensive, it is not used as a screening examination.

Intravenous Digital Subtraction Angiography

Intravenous digital subtraction angiography (IVDSA) was developed in the late 1970s as a less invasive alternative to IADSA, and reports in the early 1980s described its potential for evaluating patients with renovascular hypertension. In spite of early optimism about the procedure, many investigators have been unable to reproduce the impressive initial results.

A group of researchers in a small study of 19 patients in 1982 reported sensitivity and specificity of up to 87%, but false-positive rates ranging from 26% to 37%, which they attributed to limited spatial resolution, subtraction artifacts, and quantum noise. Other reported limitations of this technique have included obscuration of renal artery stenoses by overlap with opacified mesenteric vessels, and also suboptimal evaluation of fibromuscular lesions. A 1986 study of 45 patients found less false positives, which they attributed to technical advances and software improvements. They also reported that IVDSA grading of stenosis was accurate in 94% of cases of atherosclerotic renal artery stenosis, but in only 56% of fibromuscular stenosis. Another group of authors in a 1989 prospective study of 94 patients reported 100% sensitivity and 93% specificity for renal artery stenosis, though the 100% sensitivity was achieved in part by including inadequate examinations as positive, and the authors acknowledged the limitations of IVDSA for evaluating vessels affected by fibromuscular dysplasia. In summary, though good results can be achieved with IVDSA, its resolution is inferior compared to that of IADSA and it is less sensitive than IADSA for evaluating fibromuscular dysplasia and atherosclerotic stenosis of branch vessels. In addition, the contrast load is often substantially higher than in arteriography and requires central injection in the inferior vena cava or right atrium. For these reasons, IVDSA is not utilized as a screening examination for renovascular hypertension.

Selective Renal Vein Renin Assays

In patients with unilateral renal artery stenosis, the ischemic kidney secretes increased renin and there is relative suppression of renin release by the contralateral kidney, with resultant asymmetry in renal vein renin levels. With bilateral renal artery stenosis, there is also lateralization of renin secretion, with higher renal vein renin for the kidney with the greater degree of stenosis. This is the basis for renal vein renin assays, introduced in the 1960s, for evaluation of renovascular hypertension. Various parameters have been described, including renal vein/inferior vena cava ratios, right renal vein/left renal vein ratios. Renal vein renin assays were initially considered the best means to predict response to revascularization in patients with suspected renovascular hypertension, with the majority of studies prior to 1980 supporting the validity of this procedure. However, later studies have shown a high rate of false-negative and false-positive studies. In 1985 a group of authors reviewed 37 cases and found a false positive rate of 39% and a false negative rate of 71%. A 1986 study involving 95 patients reported a high sensitivity of 92% for a positive renal

vein renin assay but a low specificity of 42% and a high number of both false-positive and false-negative results. Another group of researchers in 1991 measured captopril-stimulated renal vein renin ratios in 133 patients and found a sensitivity of 65%, a false-positive rate of 47.8%, a positive predictive value of 18.6%, and a negative predictive value of 89.3%. A 1991 retrospective study of 25 patients with documented renal artery stenosis found that a positive renal vein renin assay had a sensitivity of 72% and a specificity of only 29%. In general, the reported high rates of false-negative and false-positive studies, as well as the susceptibility of renin assays to erroneous results due to mishandling of samples, patient hydration status, and patient medication limit the widespread use of renal vein renin assays as a screening test for renovascular hypertension.

Duplex Doppler Ultrasound

Duplex Doppler ultrasound (US) is an attractive technique as a noninvasive screening test in that it is relatively inexpensive, does not require contrast, and can be used in patients with any level of renal function. As with many of the noninvasive imaging examinations, there are numerous parameters and abnormal criteria indicating possible renovascular disease. The most frequently quoted parameters are a peak systolic velocity in the renal artery exceeding 180 or 200 cm/s and a renal artery/aortic velocity ratio exceeding 3.5. Using these parameters, early investigators have quoted sensitivities from 85% to 90% and specificity of 95%. However, many investigators have had trouble duplicating these results and have reported extremely poor sensitivities, as low as 0%.

Variations in results are largely due to technically inadequate studies and using 100 cm/s as a threshold for normal velocity, thereby producing a high number of false-positive studies. A major problem in many of these studies is that approximately 10% to 20% of patients may have technically inadequate studies secondary to obesity or overlying bowel gas. In addition, examination times have varied from 10 to 15 minutes to up to 1.5 hours. The variability in examination time has no doubt contributed to the variability in sensitivity rates reported in the literature. Doppler US is less useful than invasive angiography for diagnosing fibromuscular dysplasia and detecting accessory renal arteries.

Some reports have advocated segmental renal artery waveform analysis using measurements such as acceleration time and acceleration index, as well as "parva and tarda" waveform appearances. Using upper, middle, and lower pole segmental artery waveform analysis in the kidneys, these investigators have found the technique to be approximately 85% to 90% sensitive. An increase in acceleration time (normal <70 milliseconds) and loss of the early systolic peak (ESP) appear to be the most useful parameters. Administration of US contrast agent improves the quality of renal artery images, reduces mean examination time, and improves visualization of the entire length of the main renal arteries and accessory renal arteries. Though US contrast agents are not currently U.S. Food and Drug Administration (FDA) approved for use in the United States for this indication, European and Canadian studies have shown increased sensitivity and specificity of contrast-enhanced US for evaluating renal artery stenosis compared to standard non-enhanced US.

Because of the difficulty and time involved in the examination, duplex Doppler US should only be used in medical centers where it has proven to be reliable and where dedicated technologists and physicians are skilled in the examinations. Several recent comparative studies have demonstrated that Doppler US with or without administration of captopril or US contrast is more sensitive and specific than ACE-inhibitor scintigraphy. Doppler US may also be of use in predicting the outcomes for renal artery interventions. When resistive index values exceed 0.8, the results in terms of reducing hypertension or improving renal function are usually poor.

ACE-Inhibitor Renography and Scintigraphy

Renal scintigraphy was first used for evaluating renal function in the late 1950s. Initial attempts to use renography specifically for evaluating renovascular hypertension had a high rate of false-positive and false-negative results. Captopril was later added to the examination in an attempt to improve the accuracy of the test for diagnosing renovascular hypertension and for predicting blood pressure reduction after surgery or angioplasty. Administration of an ACE-inhibitor such as captopril leads to a decrease in glomerular filtration pressure, prolonged transit time of tubular agents such as ^{99m}Tc -MAG3, and decreased uptake of glomerular agents such as ^{99m}Tc -diethylenetriaminepentaacetic acid (Tc-DTPA). Captopril renal scintigraphy analysis is based on characterization of renal function deterioration when compared to a baseline study, with decreased glomerular filtration rate (GFR) reflected in time-activity curves. Captopril renography is therefore a functional assessment of renal perfusion and function rather than a method of directly visualizing the vasculature. The sensitivity and specificity of this examination are decreased in patients without clinical features of renovascular hypertension, and/or are also decreased in patients with bilateral renal artery stenosis, impaired renal function, and urinary obstruction. The reported sensitivity of captopril renal scintigraphy for renovascular hypertension ranges from 34% to 93%, with a meta-analysis of 14 studies between 1990 and 2000 by a group of researchers in 2001 showing a mean sensitivity of approximately 81%. There have also been inconsistent results regarding the predictive value of captopril renal scintigraphy in identifying patients who will respond to revascularization. High correlation between a positive result on captopril renal scintigraphy and reduction in blood pressure following intervention has been reported in some studies. However, the predictive value has been dismissed in other studies, with reported positive predictive values as low as 51%.

In summary, captopril renal scintigraphy has decreased sensitivity and specificity in patients with bilateral stenosis and impaired renal function, but it can be a useful tool for detecting renovascular hypertension in appropriately selected patients. As a functional evaluation of renal perfusion and

function, captopril scintigraphy can be useful to determine the physiologic sequence of a known stenosis and to assess the relative function of each kidney prior to intervention.

Magnetic Resonance Angiography

Magnetic resonance angiography (MRA) is suited for noninvasive workup of renal artery stenosis and has been widely applied for clinical practice. The reliability of MRA is not affected by the presence of bilateral renovascular disease. It is unnecessary to hydrate the patients or to stop diuretics before the examination. Three-dimensional (3D) contrast-enhanced MRA with an intravenous injection of gadolinium-based contrast agent has been the backbone of magnetic resonance imaging (MRI) examination of renal arteries, but noncontrast MRA, with steady-state free precession (SSFP) and arterial spin labeling techniques has also been used for evaluating the renal arteries.

Several investigators report using angiography as the standard of reference, with sensitivity of MRA ranging from 88% to 100% and specificity ranging from 71% to 100%. In a meta-analysis of 25 studies, the sensitivity and specificity of gadolinium-enhanced MRA were 97% and 85%, respectively. With the use of high-spatial-resolution small-field-of-view contrast-enhanced MRA techniques, it is possible to evaluate not only the main renal arteries but also the accessory renal arteries and distal stenosis. Improved gradient hardware and parallel imaging techniques have reduced acquisition times and improved spatial resolution. Recent studies have also shown high accuracy of unenhanced techniques. A group of researchers in a 2008 report comparing unenhanced SSFP MRA with computed tomography or IADSA in 26 patients found sensitivity, specificity, positive predictive value, and negative predictive value of 78%, 91%, 64%, and 96%, respectively. Another group in a 2010 report comparing an SSFP technique with contrast-enhanced MRA in 45 patients found sensitivity, specificity, positive predictive value, and negative predictive value of 75%, 99%, 75%, and 99%, respectively, for detecting renal artery stenoses >50%.

Most MRI techniques rely solely on the morphologic assessment of the vasculature. To assess the hemodynamic consequences of a particular arterial lesion, additional functional tests are sometimes required. Although still investigational, cine phase-contrast MRI flow quantification techniques in combination with 3D gadolinium-enhanced MRA appear to be feasible for detecting and determining the degree of renal artery stenosis. A combination of cine phase-contrast MRI renal flow and parenchymal volume measurements enables identification of patients who may benefit from percutaneous transluminal angioplasty and stent placement.

Gadolinium-based MRI contrast agents previously were widely believed to be well tolerated and non-nephrotoxic, even in patients with impaired renal function. However, exposure to gadolinium contrast agents in patients with renal failure and those maintained on dialysis has been linked with the development of nephrogenic systemic fibrosis (NSF). See the "Anticipated Exceptions" section below for additional information.

Computed Tomographic Angiography

Contrast-enhanced computed tomographic angiography (CTA) provides accurate anatomic images of the renal arteries with multi-detector-row helical scanners permitting acquisition of isotropic datasets that enable the reconstruction of high-resolution images in any plane. As with conventional angiography, the disadvantages of this technique are its ionizing radiation and its use of nephrotoxic contrast material. Advantages compared to IADSA include less invasiveness, faster acquisitions, and multiplanar imaging. Two studies comparing CTA with digital renal arteriography have reported the sensitivity of CTA for detecting significant stenoses (greater than 50% narrowing) to be 88% to 96% and the specificity 77% to 98%, and in one study the accuracy was 89%. In diagnosing narrowing of only the main renal arteries, one study found the sensitivity and specificity to be 100% and 98%, respectively. Normal results from CTA virtually rule out renal artery stenosis. Both maximum intensity projection (MIP) and volume-rendering techniques are useful and complementary in CT evaluation of renal artery stenosis. Secondary signs include poststenotic dilatation, renal atrophy, and decreased cortical enhancement. A threshold of 800 mm² for cortical area and 8 mm for mean cortical thickness seen on CT can be a useful morphologic marker of atherosclerotic renal disease.

Like MRA, CTA is more accurate in diagnosing proximal lesions. CTA can also be used to assess patency of renal stent grafts. A 2009 report described CTA evaluation of 95 renal artery stents — 98% of the stents were assessable on CTA, and there was 100% sensitivity and 99% specificity for detecting in-stent stenosis. Improvements in both MRA and CTA techniques in the near future are likely to render catheter angiography unnecessary in the diagnosis of renal arterial disease.

Summary

- Diagnostic imaging for hypertension depends on the index of suspicion for renovascular disease and on the patient's renal function. If clinical findings strongly suggest the possibility of renovascular disease, MRA or CTA should be performed. Duplex Doppler US or captopril scintigraphy could also be used if MRA is not desired or is contraindicated. Conventional angiography and IADSA should be reserved for confirmation and for therapeutic reasons such as angioplasty and stent placement, especially with the recent advances in the MR and CT techniques and their successful results.
- For patients with a high index of suspicion for renovascular disease and diminished renal function, gadolinium-enhanced contrast MRA is best suited to evaluate renovascular disease. However, the association of exposure to gadolinium contrast agents in patients with renal failure

with NSF warrants caution, and unenhanced MRA techniques are available as an alternative to gadolinium-enhanced MRA. Duplex Doppler US is also a preferred screening examination, especially in a medical center where the technique has proven to be reliable and where dedicated technologists and physicians are skilled in the examination and can perform it with a high degree of accuracy. Captopril renography is not a reliable test in patients with poor renal function. CTA may also be contraindicated in patients with renal insufficiency.

- Patients with hypertension and a low index of suspicion for renovascular disease most likely have "essential" hypertension that is usually easily controlled with medication. There is no need for diagnostic imaging in these patients.

Anticipated Exceptions

NSF is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited GFR (i.e., $<30 \text{ mL/min/1.73 m}^2$), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates $<30 \text{ mL/min/1.73 m}^2$. For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Abbreviations

- ACE, angiotensin-converting enzyme
- CTA, computed tomographic angiography
- IADSA, intra-arterial digital subtraction angiography
- IVDSA, intravenous digital subtraction angiography
- MRA, magnetic resonance angiography
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
☼	$<0.1 \text{ mSv}$	$<0.03 \text{ mSv}$
☼ ☼	0.1-1 mSv	0.03-0.3 mSv
☼ ☼ ☼	1-10 mSv	0.3-3 mSv
☼ ☼ ☼ ☼	10-30 mSv	3-10 mSv
☼ ☼ ☼ ☼ ☼	30-100 mSv	10-30 mSv

*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Renovascular hypertension

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Family Practice

Internal Medicine

Nephrology

Nuclear Medicine

Radiology

Urology

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of initial radiologic examinations for patients with renovascular hypertension

Target Population

Patients with a high or a low index of suspicion of renovascular hypertension ("essential" hypertension) and a normal or diminished renal function

Interventions and Practices Considered

1. Magnetic resonance angiography (MRA)
 - Abdomen with and without contrast
 - Abdomen without contrast
2. Computed tomographic angiography (CTA) abdomen with contrast
3. Ultrasound (US) kidney retroperitoneal with Doppler
4. Angiotensin-converting enzyme (ACE)-inhibitor renography
5. Intra-arterial digital subtraction angiography (IADSA) kidney
6. Renal vein renin assays
7. X-ray intravenous urography
8. Intravenous digital subtraction angiography (IVDSA) kidney

Major Outcomes Considered

Utility of radiologic procedures in the evaluation of renovascular hypertension

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis, and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid, but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Modified Delphi Technique

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The ratings are a scale between 1 and 9, which is further divided into three categories: 1, 2, or 3 is defined as "usually not appropriate"; 4, 5, or 6 is defined as "may be appropriate"; and 7, 8, or 9 is defined as "usually appropriate." Each panel member assigns one rating for each procedure per survey round. The surveys are collected and the results are tabulated, de-identified and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. Consensus is defined as eighty percent (80%) agreement within a rating category. The final rating is determined by the median of all the ratings once consensus has been reached. Up to three rating rounds are conducted to achieve consensus.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for evaluation of patients with known or suspected renovascular hypertension

Potential Harms

- Intra-arterial digital subtraction angiography (IADSA) is an invasive procedure with associated risks of vascular injury and bleeding, entails the use of iodinated contrast and ionizing radiation, and is expensive.
- The contrast load in intravenous digital subtraction angiography (IVDSA) is often substantially higher than in arteriography and requires central injection in the inferior vena cava or right atrium.
- Initially considered the best means to predict response to revascularization in patients with suspected renovascular hypertension, renal vein renin assays in later studies have shown a high rate of false-negative and false-positive results.

Gadolinium-based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, an RRL indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Contraindications

Contraindications

- Computed tomographic angiography (CTA) may be contraindicated in patients with renal insufficiency.

- Captopril renography is not a reliable test in patients with poor renal function.

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Harvin HJ, Casalino DD, Remer EM, Bishoff JT, Coursey CA, Dighe M, Eberhardt SC, Goldfarb S, Lazarus E, Leyendecker JR, Lockhart ME, Majd M, Nikolaidis P, Oto A, Porter C, Ramchandani P, Sheth S, Vikram R, Expert Panel on Urologic Imaging. ACR Appropriateness Criteria® renovascular hypertension. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 10 p. [74 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1995 (revised 2012)

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

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Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Urologic Imaging

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

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Guideline Availability

Electronic copies: Available from the [American College of Radiology \(ACR\) Web site](#) .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the [American College of Radiology \(ACR\) Web site](#) .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies:

Available in Portable Document Format (PDF) from the [ACR Web site](#) .

- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the [ACR Web site](#) .
- ACR Appropriateness Criteria® Manual on contrast media. Reston (VA): American College of Radiology; 90 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria® renovascular hypertension. Evidence table. Reston (VA): American College of Radiology; 27 p. Electronic copies: Available from the [ACR Web site](#) .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on November 15, 2004. The information was verified by the guideline developer on December 21, 2004. This NGC summary was updated by ECRI on January 5, 2006. The updated information was verified by the guideline developer on January 19, 2006. This summary was updated by ECRI Institute on May 17, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Gadolinium-based contrast agents. This summary was updated by ECRI Institute on June 20, 2007 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This NGC summary was updated by ECRI Institute on December 5, 2007. This NGC summary was updated by ECRI Institute on June 18, 2010. This summary was updated by ECRI Institute on January 13, 2011 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This NGC summary was updated by ECRI Institute on November 6, 2012.

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